UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**CASE NO. 1:17-MD-2804**
	)	
	)	**SPECIAL MASTER COHEN**
THIS DOCUMENT RELATES TO: "*Track One-B Cases*"	)	
	)	
	)	**DISCOVERY RULING REGARDING PHARMACY DATA PRODUCTION**
	)	

The MDL Court earlier entered two Orders setting out the scope of discovery of transactional dispensing data from the Pharmacy Defendants in Track One-B. *See* docket no. 3055 (ordering the Defendants to "roll out" transactional dispensing data for the entire United States from 2006 forward, first locally, then regionally, then nationally); docket no. 2976 at 2 ("Special Master Cohen will oversee this discovery"). The Pharmacy Defendants have filed a petition for writ of mandamus challenging these orders, *see* docket no. 3092; however, unless and until the appellate court overrules or modifies the Court's rulings, the parties must move forward with discovery as ordered. Accordingly, the undersigned met with the parties to determine exactly which "data fields" from the Defendants' databases must be produced.

Plaintiffs initially sought over 160 specific data fields, including many details that qualify as "protected health information" under HIPAA, up to and including patients' full names and addresses.[1] The Court's discovery orders allowed discovery of much of this information. *See, e.g.*,

[1] *See* 45 C.F.R. §164.514(b)(2) (listing 18 categories of "identifiers" of individuals, such as their names, telephone numbers, social security numbers, photographs, and so on).

docket no. 3055 at 2 ("The Court has put into place numerous protective orders specifically addressing health information protected under the Health Insurance Portability and Accountability Act ('HIPAA'), such as patient prescriptions."); docket no. 1421 at 2 (granting ***Defendants'*** request that "Track One ***plaintiffs*** will produce all opioid-related claims data not implicated by Title 42, Part 2 of the Code of Federal Regulations ('Part 2), with individual-identifying information.") (emphasis added). Nonetheless, the undersigned urged the parties to agree as much as possible to discovery of as few data fields as absolutely necessary, while still allowing: (1) Plaintiffs to undertake their "Red Flag analysis," and (2) Defendants to counter Plaintiffs' conclusions.[2]

During the course of the Special Master's discovery conference with the parties, Plaintiffs agreed to drop their request for all but 34 data fields. The Special Master overruled Defendants' objection to production of a few of these data fields (e.g., patient's birth year). The parties' negotiations and the Special Master's rulings were all on the record. The Special Master now documents the results of this process by attaching to this *Ruling* as Exhibit A the list of data fields the Defendants must produce. Notably, only a fraction of these 34 fields contain patient protected health information, and the most private identifiers will not be produced. Thus, for example: (1) a patient's name and social security number will be withheld, but she will be given a new, unique identifying number across databases to allow cross-reference; (2) her street address will not be produced, but her zip code will be; (3) her full date of birth will not be produced, but her birth year will be; and so on. The end result is that no person who obtains the data will learn what medications

[2] Plaintiffs seek to conduct a "Red Flag analysis" by having their experts examine each Defendant's data and opine whether certain prescriptions or prescription patterns should have raised a "Red Flag," such that the Defendant had an obligation to investigate the validity of the prescriptions. Defendants intend to use the same data to show Plaintiffs' analysis is faulty and/or that they did undertake all necessary and appropriate investigations.

any identifiable individual has received.

* * * * *

In addition to the data fields, the parties further agreed on the list of ***opioid*** drugs for which prescription data would be produced.[3] The parties could not agree fully during the status conference, however, on the extent of data production for ***non-opioid*** drugs. Defendants did acquiesce to provide Plaintiffs with limited prescription data for (i) a single type of sedative drug known as alprazolam, and (ii) a single type of muscle relaxant known as carisoprodol[4] – because it is known that patients receiving all three of these drugs together are more likely to be opioid addicts engaged in "doctor shopping" and in presentation of questionable or suspicious prescriptions.[5] But Defendants insist they should not be required to produce data for other non-opioid drugs.

Specifically, the Pharmacy Defendants submit that their obligations regarding non-opioid prescriptions should

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[3] Actually, the parties agreed much earlier, during litigation of Track 1A, on the list of opioids regarding which each Defendant would respond. *See, e.g.*, Walgreens' Amended Objections and Responses to Plaintiffs' First Set of Requests for Production of Documents at 6 ¶4; Walmart's Amended and Supplemental Objections and Responses to Plaintiffs' First Set Of Requests for Production, Appendix A. The same lists continue to apply. Buprenorphine is ***not*** on these lists, although Plaintiffs sought to include it in Exhibit B.

[4] Alprazolam is a type of benzodiazepine and is the active ingredient in Xanax. Carisoprodol is the active ingredient in Soma.

[5] The three drugs together are known colloquially as the "Holy Trinity" or the "Houston Cocktail." *See* Pharmacy Times, *The Perfect Storm: Opioid Risks and 'The Holy Trinity,'* http://bit.ly/HolyTrinityMDL ("'The Holy Trinity' is a drug regimen that includes at least [one] opioid, a benzodiazepine, and carisoprodol. This combination has been rising in popularity and is commonly prescribed by 'pill mills.'"); Superior HealthPlan, *Deadly Drug Combination: The Houston Cocktail*, http://bit.ly/HoustonCocktailMDL ("The Houston Cocktail, also known as the Holy Trinity, is made up of a combination of hydrocodone, alprazolam [a benzodiazepine], and carisoprodol that, when taken together, can be lethal for patients. The combination of these medications do not show clinical benefits and may be viewed as drug-seeking behavior.").

> be limited to data concerning the "Trinity" or "Holy Trinity" combinations, described by DEA in the context of enforcement efforts and by the Ohio Board of Pharmacy, as consisting of (1) alprazolam; (2) carisoprodol; and (3) either oxycodone or hydrocodone. The Pharmacy Defendants further submit that any dispensing data concerning this combination of drugs must be limited to that which is (1) filled on the same day at the same store, (2) for the same patient, (3) prescribed by the same prescriber, and (4) dispensed in 2013 and later.

Position Paper from Tara Fumerton to Special Master at 1 (Jan. 27, 2020). Defendants support their position with, among other materials, position papers and presentations made by the DEA, FDA, and Ohio Board of Pharmacy.[6] Defendants also note correctly that every addition to their data production increases their discovery cost and to some extent the invasion of their customers' privacy.

Plaintiffs argue, however, that: (a) it is not only the specific three-drug combinations listed by Defendants that can raise "Red Flags;" and (b) the limitations of same day / same store / same prescriber are too narrow. Plaintiffs assert, for example, that if a "Red Flag" is present when a patient obtains three same-***day*** prescriptions for Oxycontin (opioid), Soma (carisoprodol), and Xanax (benzodiazepine), then a "Red Flag" is equally present for a patient obtaining three same-***week*** prescriptions for Oxymorphone (different opioid), Soma (carisoprodol), and Valium (different benzodiazepine). Plaintiffs assert they should be allowed to discover *all* dispensing data for prescriptions of 14 types of benzodiazapines, 4 muscle relaxants, and 11 sleep aids, because it is known that patients receiving any combination of these categories of drugs (including only just two-drug combinations) are very often also drug-seeking; therefore, these prescriptions are all necessary

[6] *See, e.g.*, DEA PowerPoint presentation, "DEA Perspective: Pharmaceutical Use & Abuse" (2013) (referring to the "Cocktail" or "Trinity" as being composed of "Hydrocodone, Soma®/carisoprodol, [and] Alprazolam/Xanax®").

for a full "Red Flag" analysis. *See* Exhibit B (Plaintiffs' list of drugs they want for a "Red Flag" analysis). Plaintiffs support their position with, among other material, Defendants' own documents.[7]

The Special Master has reviewed all of the materials submitted by the parties and considered carefully the extent to which the discovery Plaintiffs seek is proportional to the needs of the case, including patient privacy interests. *See* Fed. R. Civ. P. 26(b)(1). The Special Master concludes as follows:

- In addition to producing the 34 fields of transactional dispensing data for the relevant opioid drugs, Defendants shall produce data for: (i) the 14 benzodiazepines, and (ii) the 4 muscle relaxers, that are listed by Plaintiffs in Exhibit B. Defendants need not produce transactional

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[7] *See, e.g.*, "Walgreens Pharmacist GFD [Good Faith Dispensing] Review Coaching Opportunities" PowerPoint Presentation at 13 (2013) (areas of concern include "Cocktails identified as an Opiate ***or*** Hydrocodone, Benzodiazepine and Carisoprodol, where the Benzodiazepine and Carisoprodol (***or*** Gabapentin) ***were both dispensed within 12 days plus of the Opiate dispensing date***.") (emphasis added). *See also Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195 Decision and Order*, 77 Fed. Reg. 62,316 at n.102 (DEA Oct. 12, 2012) ("The Respondents contend that the [two-drug] oxycodone-alprazolam combination was not a red flag in 2010, when most of the allegedly wrongful dispensing occurred. * * * Contrary to this contention, [Diverson Investigator] Langston testified that the combination of oxycodone and Xanax (the brand name for alprazolam) was a red flag of diversion for at least "[a] couple of years ago.").

Notably, Defendants' Position Paper cites a video produced by the Ohio Board of Pharmacy to support their argument that "Red Flags" are raised ***only*** by the ***two*** combinations of: (1) alprazolam, (2) carisoprodol, and (3)(a) hydrocodone or (b) oxycodone. In fact, however, the Board's video, "Red Flags of Prescription Drug Diversion," states: "Drug addicts will often combine prescription medicines to intensify the effect. This is referred to as a 'drug cocktail,' and *involves mixing an opiate with a benzodiazepine and a muscle relaxant*."
See https://www.youtube.com/watch?v=WY2I2JE3Hqs at 5:55-6:00 (emphasis added). The video goes on to note that addicts use street names to refer to certain cocktails, such as "Trio" or "Trinity" for hydrocodone-alprazolam-carisoprodol, and "Holy Trinity" for oxycodone-alprazolam-carisoprodol. *Id.* at 6:00-6:20. But the video clearly states that the "Trinity" and "Holy Trinity" combinations are not the only "Red Flags." Further, the same video shows that limiting data to prescriptions from the same prescriber or filled on the same day is inappropriate. *Id.* at 7:22-7:52 (showing that multiple prescribers can be a "Red Flag" for doctor shopping, and that addicts present prescriptions for cocktail drugs over several days).

dispensing data for the 11 sleep aid medications requested by Plaintiffs. To quote again the Ohio Board of Pharmacy, the most glaring "Red Flag" prescription combinations involve "mixing an opiate with a benzodiazepine and a muscle relaxant." *See* footnote 7. The materials submitted to the Special Master do not support inclusion of sleep aid combinations in the "Red Flag cocktail menu."

- Each Defendant may choose to simply produce all of its data for benzodiazepine and muscle relaxer prescriptions, without limitation; or instead produce only data for such prescriptions where it dispensed a benzodiazepine or muscle relaxer to a patient and also dispensed an opioid to the same patient within 14 days (before or after).[8]

* * * * *

Finally, the Special Master rules as follows regarding the timing of Defendants' data production and Plaintiffs' identification of "Red Flag" prescriptions.

- Defendants shall produce all of the required data on or before March 2, 2020.
- As soon as possible thereafter, but no later than March 30, 2020, Plaintiffs shall identify for

[8] In other words, each Defendant has two choices. First, it may simply produce data for ***all*** of its prescriptions for the listed benzodiazepines and muscle relaxers, and let Plaintiffs figure out which were given to patients who also received recent prescriptions for opioids. Second, a Defendant may instead filter its data and produce only its prescriptions for the listed benzodiazepines and muscle relaxers that it dispensed to a patient who ***also*** received from it a prescription for opioids within a 14-day plus-or-minus window. This gives each Pharmacy Defendant options to tailor, in part, its own discovery burden. That said, the deadlines discussed below may limit a Defendant's choice, if applying the data filter causes data production to take longer.

The Special Master adds that giving Defendants the option of a more complicated filter, such as producing non-opioid prescriptions only when the patient received ***both*** a benzodiazepine ***and*** a muscle relaxer within a 14-day plus-or-minus window of an opioid prescription, is not warranted and possibly unworkable. Last, as stated earlier, all prescription data shall date back to 2006. *See* docket no. 3055.

Defendants the prescriptions they (and their experts) conclude should have been "Red Flagged" as suspicious, and investigated or not filled.

- As soon as possible thereafter, but no later than 14 days from the date of Plaintiffs' "Red Flag" identification, Defendants shall produce, for all earlier-supplied prescriptions, any additional data fields upon which they or their experts intend to rely in defending against Plaintiffs' claims.[9]

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Any objection to this *Ruling* must be filed on or before January 30, 2020. Unless and until the Court sustains an objection, or this *Ruling* is affected by an Order issued by the Sixth Circuit Court of Appeals in response to the Defendants' petition for writ of mandamus, the parties must proceed in accordance with this *Ruling*. A successful objection must demonstrate abuse of discretion. *See* Fed. R. Civ. P. 53(f)(5); *Order of Appointment* (docket no. 69) at 5.

RESPECTFULLY SUBMITTED,

/s/ David R. Cohen
David R. Cohen
Special Master

Dated: January 27, 2020

[9] At the discovery conference, Defendants stated they might want to produce ***more than*** the agreed-upon 34 data fields, in order to defend themselves, depending on the results of Plaintiffs' "Red Flag" analysis; but they would not know their position until after having received the analysis. Accordingly, the parties agreed that: (1) Defendants could amend their data production with additional fields for all prescriptions in response to Plaintiffs' list of "Red Flag" prescriptions; and (2) when countering Plaintiffs' claims as the case goes forward, Defendants would not be allowed to rely upon any data fields they did not produce.

Exhibit A – List of Data Fields the Pharmacy Defendants Must Produce

No.	Data Field
1	Drug name
2	NDC number
3	Date filled
4	Quantity dispensed
5	Dosage form
6	Days' supply
7	Prescriber's name
8	Prescriber's DEA number
9	Dispensing pharmacist
10	Patient Zip Code
11	Patient ID # (Unique ID)
12	Quantity prescribed
13	Number of refills authorized (if any)
14	Diagnostic code
15	Method of payment
16	Patient paid amount
17	Whether prescription covered by third-party payor
18	Control / Non-Control ratio
19	Pharmacy DEA #
20	Pharmacy Store #
21	Pharmacy address (at the zip code level or finer)
22	Prescriber address (at the zip code level or finer)
23	Prescription Date written
24	Refill indicator (whether the Rx is a refill or the original)
25	Prescriber Specialty
26	Rejection indicator (whether the pharmacy rejected to fill)
27	Prescriber's NPI Number
28	Patient DOB Year (or age)
29	DEA Override
30	DEA Schedule (Same as Control/Non-Control)
31	Dispense Hour
32	Dispense Minute
33	Drop Off Hour
34	Drop Off Minute

Exhibit B - List of Drugs Plaintiffs want for a "Red Flag" analysis

	A	B
1	**Drug Category**	**Base Drug**
2	Benzodiazepines	alprazolam
3	Benzodiazepines	chlordiazepoxide
4	Benzodiazepines	clobazam
5	Benzodiazepines	clonazepam
6	Benzodiazepines	clorazepate
7	Benzodiazepines	diazepam
8	Benzodiazepines	estazolam
9	Benzodiazepines	flurazepam
10	Benzodiazepines	lorazepam
11	Benzodiazepines	midazolam
12	Benzodiazepines	oxazepam
13	Benzodiazepines	quazepam
14	Benzodiazepines	temazepam
15	Benzodiazepines	triazolam
16	Muscle relaxers	Carisoprodol
17	Muscle relaxers	Cyclobenzaprine
18	Muscle relaxers	orphenadrine
19	Muscle relaxers	tizanidine
20	Opioid	Codeine
21	Opioid	Dihydrocodeine
22	Opioid	Fentanyl
23	Opioid	Hydrocodone
24	Opioid	Hydromorphone
25	Opioid	Levorphanol
26	Opioid	Meperidine
27	Opioid	Morphine
28	Opioid	Opium
29	Opioid	Oxycodone
30	Opioid	Oxymorphone
31	Opioid	Tapentadol
32	Opioid Treatment	Buprenorphine
33	Opioid Treatment	Methadone
34	Sleep Aid	doxepin
35	Sleep Aid	estazolam
36	Sleep Aid	eszopiclone
37	Sleep Aid	flurazepam hydrochloride
38	Sleep Aid	ramelteon
39	Sleep Aid	suvorexant
40	Sleep Aid	temazepam
41	Sleep Aid	trazodone
42	Sleep Aid	triazolam
43	Sleep Aid	zaleplon
44	Sleep Aid	zolpidem tartrate